REMARKS

After entry of this amendment, claims 6-7, 13, and 17-21 are pending. Claims 8-12 are withdrawn. Claims 1-7 and 13-18 are rejected. Claim 19 is objected to. Claims 1-5, 8-12 and 14-16 are canceled without prejudice. Applicants reserve their right to prosecute subject matter of the canceled claims in subsequent applications.

The specification has been amended to insert sub-headings and to delete embedded hyperlinks.

Claims 6-7, 13 and 17-19 have been amended to delete recitation of non-elected sequences.

Claims 6-7, and 18 have been amended to recite the nucleic acid sequence comprising a given nucleotide sequence and deleting "consists of". Support for these amendments is in the specification on page 3, line 19.

Claim 13 has been amended to delete the word "conveniently".

New claims 20 and 21 have been added to recite kits comprising particular nucleic acids of the invention. Support is in the specification on page 6, paragraph 1, page 7, paragraph 2, and claim 13 as originally filed.

No new matter has been added by these amendments.

Election/Restriction

The restriction election to claims 1, 2,4-7 and 13-16 of Group X has been confirmed. Claim 3 has been included into Group X since it also recites SEQ ID NO:27.

The Examiner requests the claims be amended to delete recitation of non-elected sequences, and this has been done.

Specification

The specification has been objected to for the informalities of lacking sub-headings. Applicants have amended to specification to add the sub-headings.

The specification was also objected to for containing a hyperlink, and this has been deleted from page 12.

Claim Objections

Claims 4, 14 and 19 were objected to. Claims 4 and 14 have been canceled making these objections moot. Claim 19 has been amended to delete recitation of non-elected sequences and to make it independent, thereby overcoming this objection.

Claim Rejection under 35 USC § 101

Claims 1-5 and 14-16 are rejected under 35 USC § 101 because the claimed invention allegedly is directed to non-statutory subject matter. Claims 1-5 and 14-16 have been canceled making this rejection moot.

Claim Rejections under 35 USC § 112, second paragraph

Claims 1-7 and 13-18 are rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. Applicants respectfully disagree with this rejection.

Regarding the language of the claims, Applicant points out that what is required by the second paragraph of section 112 is that the claims set out and circumscribe the particular area which the patent applicant regards as his invention with a reasonable degree of precision and particularity. *In re Moore*, 439 F.2d 1232 (CCPA 1971). "[A]cceptability depends on 'whether one of ordinary skill in the art would understand what is claimed . . . in light of the specification,' even if experimentation may be needed." *Andrew Corp. v. Gabriel Electronics, Inc.*, 847 F.2d 819, 821 (Fed. Cir. 1988) (citing *Seattle Box Co. v. Inducstrial Crating & Packing*, 731 F.2d 818, 826 (Fed. Cir. 1984)), *cert. denied*, 488 U.S. 927 (1988).

The claims relate to methods for selecting plants that have an impaired silencing pathway. The method involves identifying the presence of a transcript, which the applicant's have discovered is produced in plants which are impaired in their ability to silence genes. Also claimed is a kit which comprises a "labelled" sequence capable of detecting said transcript.

As mentioned in the application as filed on page 1, it has been demonstrated that plants contain mechanisms that in effect silence, i.e. switch off, the expression of genes. Such silencing has been divided into two categories known as transcriptional gene silencing (TGS) and post-transcriptional gene silencing (PTGS) respectively. One difference between these two silencing systems is that TGS appears to be inherited from generation to generation whereas, PTGS

appears not to be inherited and thus a gene which is silenced in one generation can become active in the next and then subsequently be silenced again.

One major problem with gene silencing all too clear to the skilled biotechnologist is that once a transgene of interest has been inserted into a plant, there is always the possibility that the transgene may be silenced, and thus fail to produce the desired product, by the plants endogenous silencing mechanisms. The present invention seeks to address this problem by identifying those plants which are unable to silence genes because the plant's endogenous silencing mechanism is somewhat impaired.

The applicants invention now allows the identification of plants having an impaired silencing mechanism, such that these plants can be used with more confidence, in that any transgene of interest inserted into the "impaired silencing" plant, will not be silenced by the plant's endogenous silencing mechanisms.

The identification of the desirable "impaired silencing" plants is achieved via the detection of an RNA transcript, which transcript is only present in the plants where silencing is impaired.

The invention was made following the applicant's discovery that when two sets of plants were compared, the plants with a functional silencing pathway did not produce particular mRNA transcripts whereas, the plants that were impaired in silencing did produce the transcript.

Thus, the sequences as described in claims 1 to 4 which can hybridise with the transcript and can be used in the methods defined in those claims to identify the impaired silencing plants. Also, these sequences can be used to generate primers for use in the method of claim 5 and the sequences can be labelled for use in a kit, which kit can be used in the claimed methods.

Claims 1-5 and 14-16 have been canceled, making this rejection moot regarding these claims.

Claims 6 and 17-18 have been amended to recite a nucleic acid "comprising" a nucleotide sequence as described rather than "consists of". Claim 13 has been amended to delete the word "conveniently". Claims 17-18 have been amended to delete recitation of non-elected sequences and to delete recitation of the "RB consists of at least 50 (or 100) nucleotide residues".

These amendments overcome these rejections or make them moot.

Claim Rejection under 35 USC §112, first paragraph

Claims 1-7 and 13-18 are rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the written requirement. Applicants respectfully disagree with this rejection.

The legal standard for meeting the written description requirement under section 112, first paragraph, is whether "the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar,* 935 F.2d 1555, 1563-64, 19 USPQ2d 1111,1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

The patent application need not teach what is already known to those of ordinary skill in the art (*Hyatt v. Boone*, 146 F.3d 1348, 47 USPQ2d 1128(Fed. Cir. 1998) citing *In re Eltgroth*, 419 F.2d 918, 921, 164 USPQ 221, 223 (CCPA 1970).

Claims 1-5 and 14-16 have been canceled making this rejection moot regarding these claims.

Claims 6-7, 13 and 17-18 have been amended to delete recitation of non-elected sequences. The Examiner acknowledges on page 9 of the Office Action, that BACF7N22 (GenBank Accession No. AF058825) is at least 80% identical to an aligned component sequence of SEQ ID NO:27. Thus the claims are supported by at least one example.

Claim Rejection under 35 USC § 112, first paragraph

Claims 1-7 and 13-18 are rejected under 35 USC § 112, first paragraph, as allegedly being enabled for SEQ ID NO:27, but not enabled for other nucleic acids or the method comprising probing the RNA preparations with other nucleic acids. Applicants respectfully disagree with this rejection.

Enablement of a disclosure "is not precluded by the necessity for some experimentation such as routine screening." In re Wands, 858 F.2d 731, 736-7 (Fed. Cir. 1988) (citations omitted). The experimentation necessary must not be undue. Id. at 737. Undue experimentation

is experimentation that would require a level of ingenuity beyond what is expected from one of ordinary skill in the field. Fields v. Conover, 170 USPQ 276, 279 (CCPA 1971). The factors that can be considered in determining whether an amount of experimentation is undue have been listed in Wands, 858 F.2d at 737. Among these factors are: the amount of effort involved, the guidance provided by the specification, the presence of working examples, the amount of pertinent literature and the level of skill in the art. The test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine. Id.

The relevant inquiry for determining whether the scope of the claims is commensurate with the specification is "whether the scope of enablement provided to one of ordinary skill in the art by the disclosure is such as to be commensurate with the scope of protection sought by the claims." In re Moore, 439 F.2d 1232, 1236 (CCPA 1971) (emphasis added). "A patent need not teach, and preferably omits, what is well known in the art." Hybridtech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986), cert. Denied, 480 U.S. 947 (1987).

While predictability of the art can be considered in determining whether an amount of experimentation is undue, mere unpredictability of the result of the experiment is not a consideration. Indeed, the Court of Customs and Patent Appeals has specifically cautioned that the unpredictability of the result of an experiment is not a basis to conclude that the amount of experimentation is undue (see In re Angstadt, 190 USPQ 214 (CCPA 1976)).

Claims 1-5 and 14-16 have been canceled, making this rejection moot regardin these claims. Claims 6-7, 13 and 17-18 have been amended to delete recitation of non-elected sequences. Further, the claims are supported by the specification in that BACF7N22 (GenBank Accession No. AF058825) has the necessary sequence requirements.

The applicant's identification of the sequences described in the application has provided one skilled in the art with a mechanism for detecting such desirable plants. The application refers to the sequences initially identified and it is well within the capabilities of one skilled in the art, once presented with such information, to determine suitable variants based on a structural similarity to those specifically presented. Once such variants have been generated, it is equally

within the capabilities of the skilled person to apply those variants to the methods of the invention to identify those sequences of equal function to the specifically disclosed sequences.

In addition to this, as the methods of the invention have at their core, the detection of a particular transcript which is present in such silencing impaired plants, it is equally apparent to the skilled person that the probes used to detect said transcript can be as small as 50 nucleotides and as large as the specifically disclosed sequence or the variant based on the specifically recited percentage identity.

Thus, the claims are enabled by the specification as filed.

Claim Rejection under 35 USC § 102

Claims 1-5 and 14-16 are rejected under 35 USC § 102(b) as allegdly anticipated by Dante (GenEMBL Accession No. AF08825, 1988).

Claims 1-5 and 14-16 have been canceled, thereby making this rejection moot.

CONCLUSION

The above comments and amendments put the application in form for allowance.

Respectfully submitted,

Mary Kakefuda

Syngenta Agribusiness Biotechnology Research, Inc.
P. O. Box 12257
3054 Cornwallis Road
Research Triangle Park, NC 27709-2257

Mary Kakefuda
Attorney for Applicants
Registration No. 39,245
Telephone: 919-765-5071

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